

# Medical Devices: Marketing Your Skills and Ideas

Dennis Falkenstein  
September 15, 2009

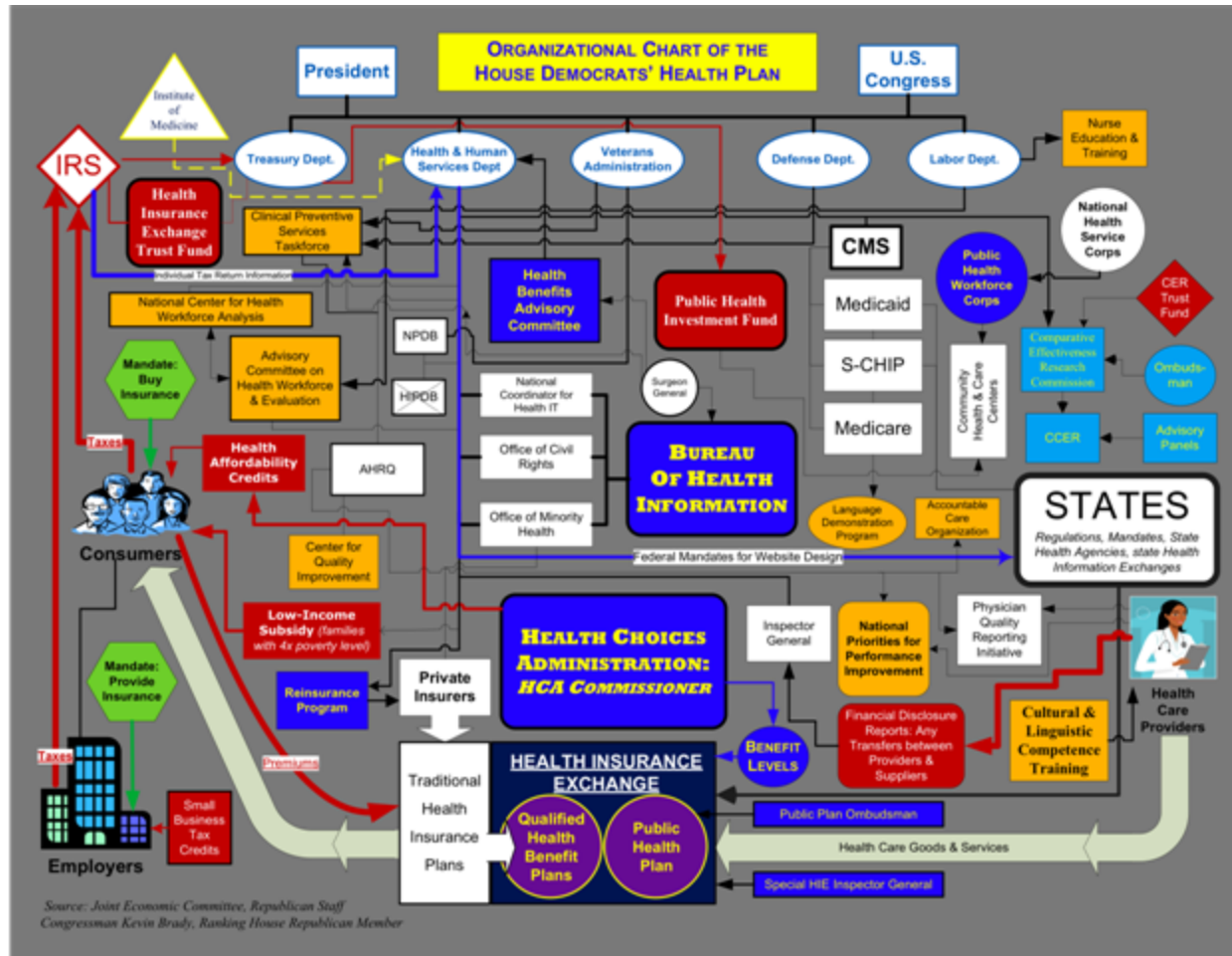
# Outline

- Short History of Medical Innovations
- Medical Business or Information Business?
- Cost Containment as a Driver
- You Have an Innovative Device, Now What?
- Market Plan to Business Plan
- Medical Market Specifics

# What this lecture is NOT

- Town Hall Meeting to promote National Health Care
- Tea Party in opposition to National Health Care

# Democratic Health Care Plan



# Republican Alternative

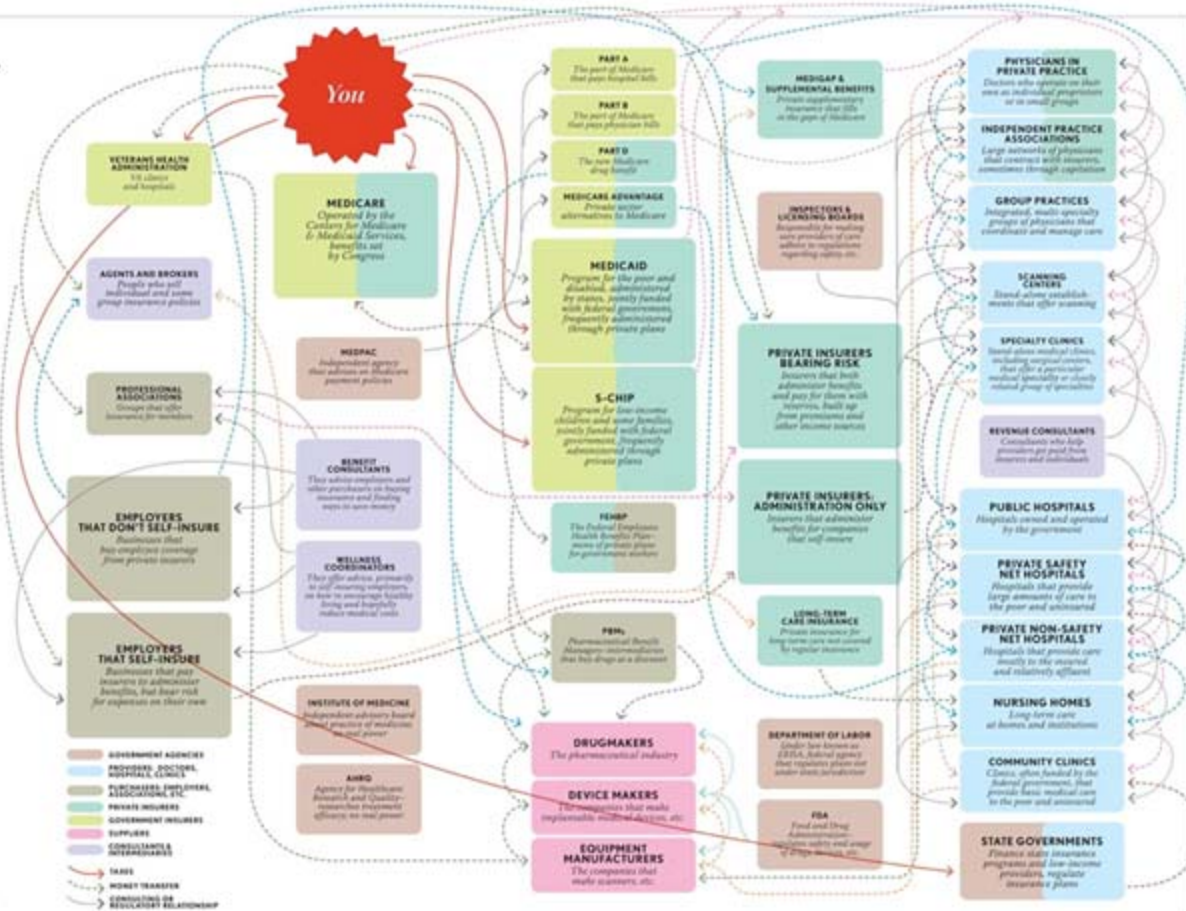
## Your Health Care System: A Map

**I**F YOU'RE TRYING to pin down a moment from 1994 when the fate of the Clinton health care plan was sealed, you could do worse than January 25. On that night, then-Senator Bob Dole responded to the president's State of the Union address. Clinton had hoped to use the speech to help sell his proposal. Dole used his response to help kill it. And he did it primarily not through what he said, but what he showed on camera.

Dole brought with him a chart, depicting how American health care would work if the Clinton plan came into effect. And it was not a pretty picture. Lines were all over the place. The boxes were full of confusing acronyms and scary-sounding institutional titles like "National Health Board" and "Regional Health Alliance." The chart had actually come from a colleague, then-Republican Senator Arlen Specter, who'd asked a staffer to draw it so he could better understand what Clinton had in mind. But Specter—and, soon enough, his Republican colleagues—quickly saw the chart as an effective propaganda weapon.

The impression of the chart was accurate enough: The Clinton plan was tremendously complicated. And given how many of the old Republican arguments against health reform are resurfacing this year, it's likely we'll be seeing a similar chart sometime this summer. But these charts leave out one key fact: The U.S. health care system is already a mind-numbing web of institutions, agencies, and businesses. And, while that may be self-evident to anybody who's ever had to handle a billing dispute between insurer and hospital, it's easy to lose sight of that in the scream of congressional debate. So, just to keep this very relevant piece of information in mind, we've drawn up our own chart—of American health care, as it is now. And, just to make sure we weren't getting it wrong, we got some help from our friends at the Henry J. Kaiser Family Foundation.

JONATHAN COHEN



# The Real Medical Tea Party 1846

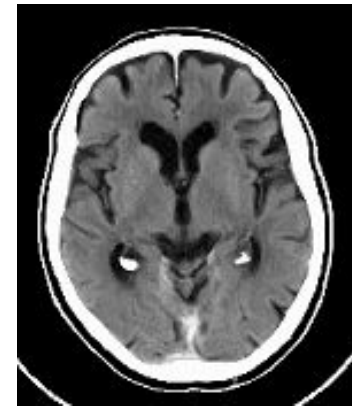
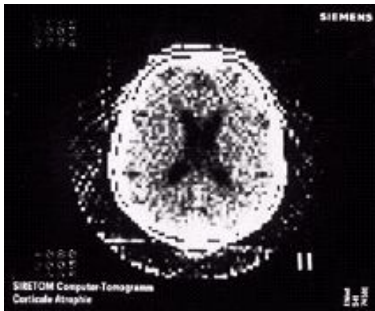
# Ether and the Beginnings of Exploratory Surgery 1846



# 1972 CT Scan 1979 Nobel Laureat to Hounsfield, EMI

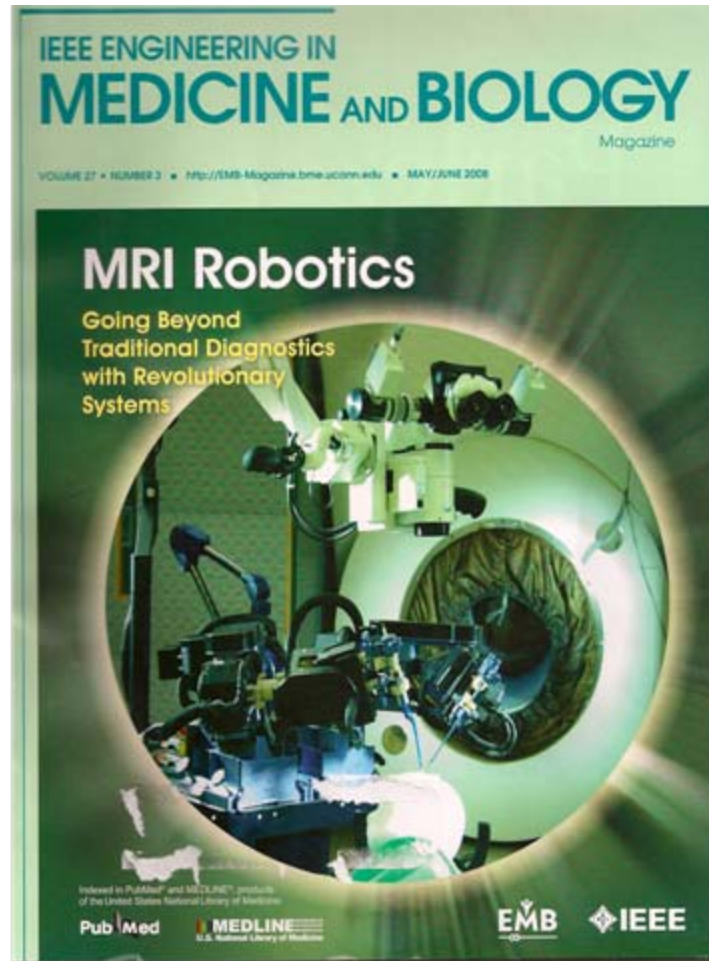


I'm Looking Through You

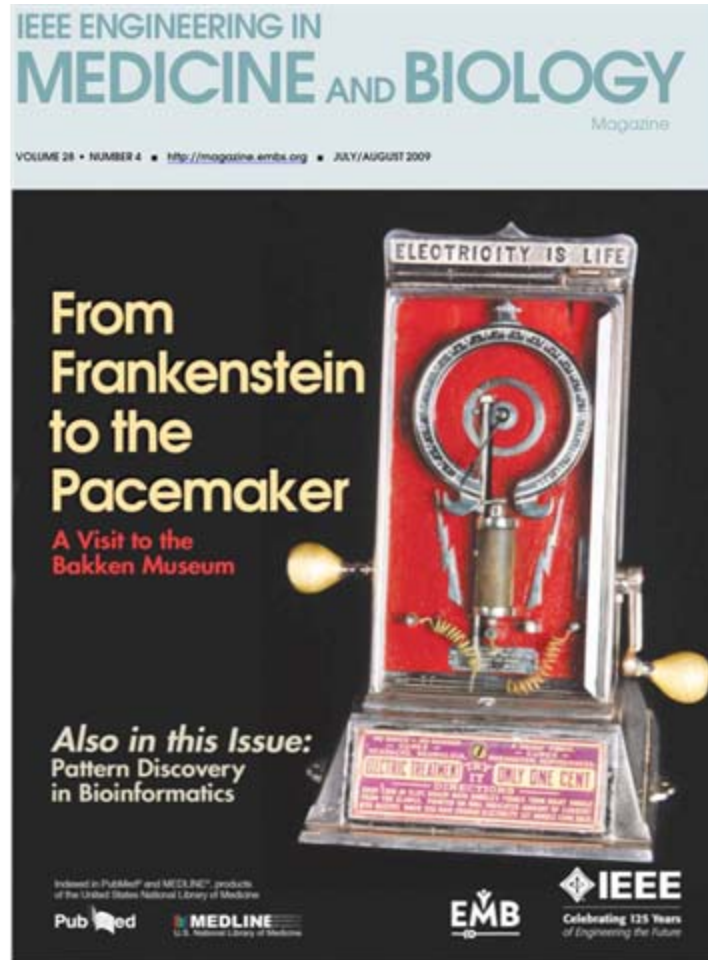




# Plethora of ancillary devices



# EMB July August 2009



# The bionic contact lens

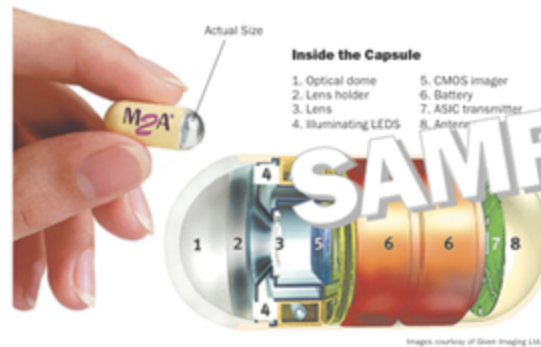


# Innovations in Imaging

Reprinted from **THE WALL STREET JOURNAL**.

THURSDAY, AUGUST 15, 2002

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## To Avoid Surgery, Eat This Camera

*More Doctors Get Inside View  
Of the Body With Video Pill;  
Close-Ups of a Tumor Site*

By MABELYN CHASE

**K**RISTEN PARSKE WAS TIRED of not knowing what was wrong with her. The 33-year-old homemaker was dangerously anemic from internal bleeding and had undergone a colonoscopy, barium X-rays and six other uncomfortable

or even surgery to figure out what is wrong. The problems that can strike include ulcers, tumors, leaky vessels and inflammatory conditions like Crohn's disease and irritable bowel syndrome. But the upper intestine is hard to see with conventional imaging tools. "The 22 feet between the stomach and colon has been a black box," says Gavriel Meron, chief executive of Given Imaging Inc., the Yocneam, Israel, company that makes the technology.

The tiny disposable camera is plastic shell, known as a video pill. It is swallowed and passes through the digestive tract, taking pictures of the

in 24 states, 17 of those with Medicare coverage, plus Washington, D.C., Puerto Rico and the U.S. Virgin Islands.

Because it is new, the video pill is mostly used after conventional tests have failed, says Robynne Chutkan, gastroenterologist at Georgetown University Hospital in Washington, D.C. "It already has carved a niche for itself in solving the mystery of obscure bleeding whose source is unknown."

Capsule endoscopy is "an amazing technology," says Ms. Parske's surgeon, Gregg Jossart. He sees a number of patients like Ms. Parske for whom "it will mean quicker diagnosis and cure."

Ms. Parske swallowed the smooth plastic capsule, which is like an oversize vitamin, and donned a thick Velcro belt loaded with a battery pack and a Walkman-size recording device. Electronic leads were attached to her torso. Over the next eight hours, she was free to stroll, eat or drink as the device meandered through her body, taking 60,000 flash pictures—two per second—and transmitting the pictures to the recording device. The single-use capsule passed out painlessly after 24 hours.

Then she returned the gear she had worn to her hospital, California Pacific Medical Center in San Francisco, where gastroenterologist Kenneth Binmoeller and nurse Martie Mattson loaded the data recorder onto a workstation.

### 'Fantastic Voyage'

On the screen, views of her body's interior unfolded like scenes from the 1966 sci-fi film "Fantastic Voyage," where doctors explore the body in a tiny submarine. Her intestine, a pulsing, walled tunnel, was marbled with vessels resembling the canals on Mars. "It's like being there," said Ms. Mattson while reviewing the video, freezing a frame. The procedure took 24 hours, 33 minutes and 16 seconds.

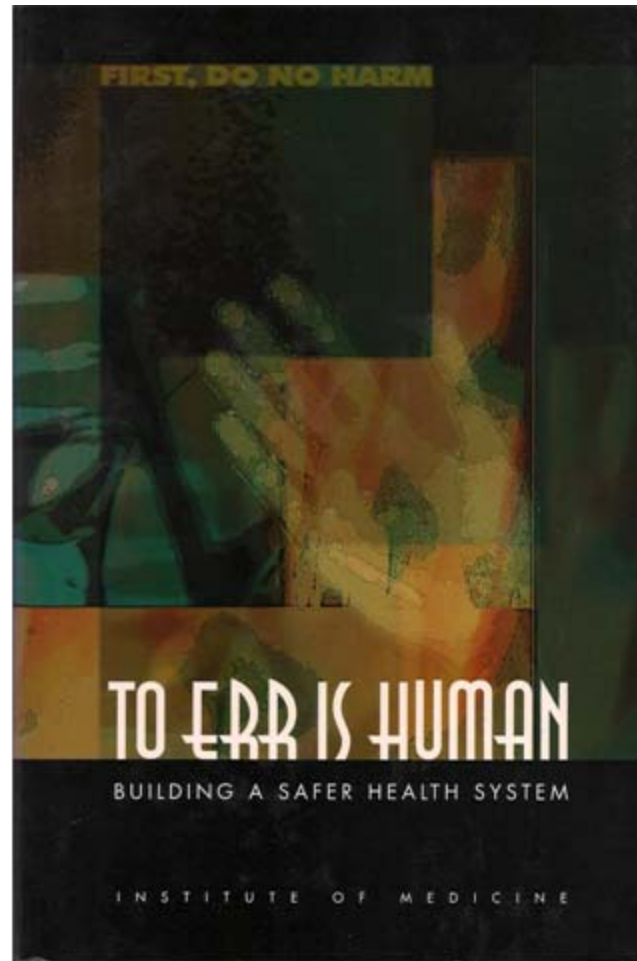
# Knowledge for decision assistance

- Early work in area of EKG analysis by computer
- Cardiac ejection fraction calculations
- Mammography reading assistance
- Care Flow
- Contraindications of drugs

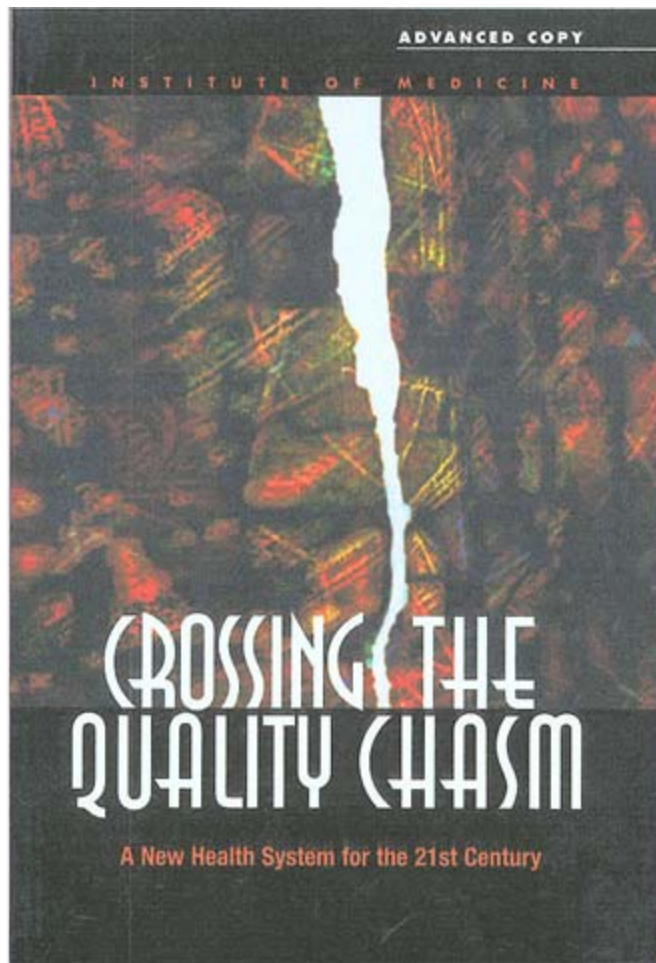
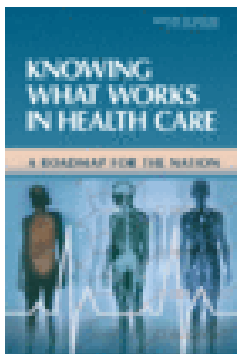
Medical business is really information, or...



# Institute of Medicine 2001



# IOM Resources





# Short History

- Non Invasive Diagnosis and Treatment
  - X-ray imaging, CT scanner, MRI, pharmaceuticals
- Cellular imaging or DNA indicators
- ATM laboratory
- Or?

# The Future Clinical Lab?



# The Business Plan

- Essential element of any business
- Necessary for raising capital
- Necessary to determine direction of company; mission, vision
- Reference of measure of progress
- Points to alternative directions (Plan B)

# Elements of a Business Plan

- Description of company and product/service offering
- Market Plan
- Revenue projections
- Operation expenses
- Results/Profits/Milestones
- Management team
- Supporting Documents

# Elements of a Business Plan

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# Market plan

- Answers the feasibility of business
- Based on market needs/wants
- Product value
- Market size
- Reimbursement issues
- Regulatory issues
- Market sustainability
- Distribution/sales channel
- Competition
- Replacement technology
- Risks, SWAT, PEST

# Specifics of medical market

- Well defined customer universe
- Well defined usage requirements
- Price determined by LCA (Lowest Cost Alternative)
- Regulatory compliance
  - Most medical devices require FDA review (clearance or approval)
  - HIPAA requirements; Health Insurance Portability and Accountability Act
  - Sarbanes-Oxley; SOX

# Various medical engagements

- Medical device to end user
- Accessories to medical device
- Software for medical device or application
- Subsystems for medical device
- Components of medical device



# Complexity varies with various engagements

Reimbursement

- Medical device to end user
- Accessories to medical device
- Software for medical device
- Subsystems for medical device
- Components of medical device

Regulatory

Cost

Involvement

Constraints

Driven

HIGHEST

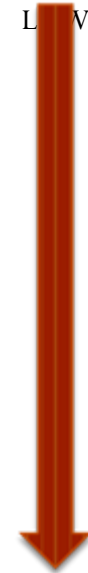
LOWEST

HIGHEST

LOWEST

HIGHEST

LOWEST



# Various medical engagements

- **Medical device to end user**
- Accessories to medical device
- Software for medical device or application
- Subsystems for medical device
- Components of medical device

# Specifics of medical market

- Well defined customer universe
  - Hospitals
  - Clinics
  - Private physicians
  - Nursing homes
  - Home market

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# Determinants of device selling price

- Medical market is NOT cost plus
- Need to determine the value of your device and it must be greater than the cost of your product; include all costs; direct and indirect
- Selling price as a function of the value;
  - More patients per unit time
  - Less labor per procedure
  - Less errors per procedure
  - Less complications or morbidity
  - Higher cure rate

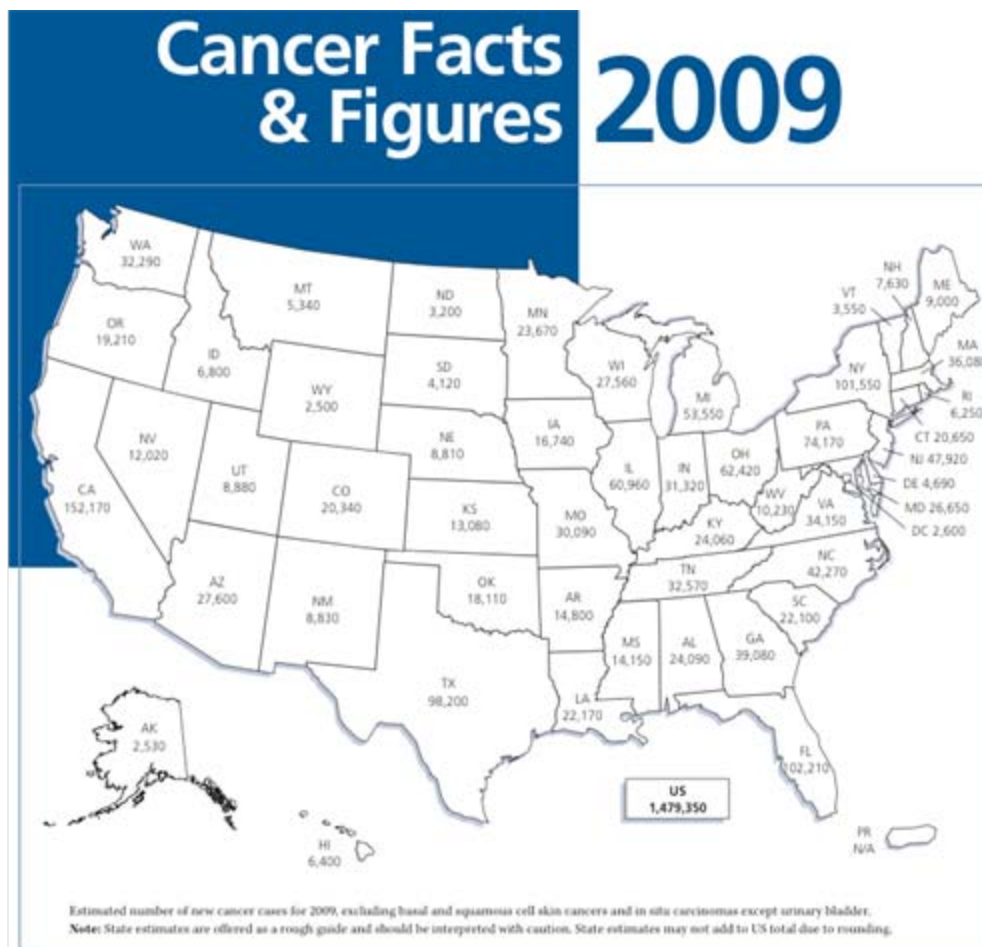
# Macro approach

- National incidence numbers on disease
  - Specific segmentation of disease
  - Cure rates, diagnostic specificity and sensitivity
  - Complications
  - Care flow
- Costs for care
- Reimbursement levels

# Specifics of medical market

- Well defined usage requirements
  - Volume data available on many diseases and treatments
  - Government sites, professional societies, patient groups
  - Data can be localized to individual customer catchment areas

# American Cancer Society





# Screening Guidelines

## Screening Guidelines for the Early Detection of Cancer in Average-risk Asymptomatic People

Cancer Site	Population	Test or Procedure	Frequency
<b>Breast</b>	Women, age 20+	Breast self-examination	Beginning in their early 20s, women should be told about the benefits and limitations of breast self-examination (BSE). The importance of prompt reporting of any new breast symptoms to a health professional should be emphasized. Women who choose to do BSE should receive instruction and have their technique reviewed on the occasion of a periodic health examination. It is acceptable for women to choose not to do BSE or to do BSE irregularly.
		Clinical breast examination	For women in their 20s and 30s, it is recommended that clinical breast examination (CBE) be part of a periodic health examination, preferably at least every three years. Asymptomatic women aged 40 and over should continue to receive a clinical breast examination as part of a periodic health examination, preferably annually.
		Mammography	Begin annual mammography at age 40.*
<b>Colorectal<sup>1</sup></b>	Men and women, age 50+	Fecal occult blood test (FOBT) <sup>2</sup> with at least 50% test sensitivity for cancer, or fecal immunochemical test (FIT) with at least 50% test sensitivity for cancer, or	Annual, starting at age 50
		Stool DNA test	Interval uncertain, starting at age 50
		Flexible sigmoidoscopy, or	Every five years, starting at age 50
		Fecal occult blood test (FOBT) <sup>2</sup> and flexible sigmoidoscopy, <sup>3</sup> or	Annual FOBT (or fecal immunochemical test (FIT)) and flexible sigmoidoscopy every five years, starting at age 50
		Double-contrast barium enema (DCBE), or	Every five years, starting at age 50
		Colonoscopy	Every 10 years, starting at age 50
<b>Prostate</b>	Men, age 50+	CT colonography	Every five years, starting at age 50
		Digital rectal examination (DRE) and prostate-specific antigen test (PSA)	Health care providers should discuss the potential benefits and limitations of prostate cancer early detection testing with men and offer the PSA blood test and the digital rectal examination annually, beginning at age 50, to men who are at average risk of prostate cancer, and who have a life expectancy of at least 10 years. <sup>4</sup>
<b>Cervix</b>	Women, age 18+	Pap test	Cervical cancer screening should begin approximately three years after a woman begins having vaginal intercourse, but no later than 21 years of age. Screening should be done every year with conventional Pap tests or every two years using liquid-based Pap tests. At or after age 30, women who have had three normal test results in a row may get screened every two to three years with cervical cytology (either conventional or liquid-based Pap test) alone, or every three years with an HPV DNA test plus cervical cytology. Women 70 years of age and older who have had three or more normal Pap tests and no abnormal Pap tests in the past 10 years and women who have had a total hysterectomy may choose to stop cervical cancer screening.
<b>Endometrial</b>	Women, at menopause	At the time of menopause, women at average risk should be informed about risks and symptoms of endometrial cancer and strongly encouraged to report any unexpected bleeding or spotting to their physicians.	
<b>Cancer-related checkup</b>	Men and women, age 20+	On the occasion of a periodic health examination, the cancer-related checkup should include examination for cancers of the thyroid, testicles, ovaries, lymph nodes, oral cavity, and skin, as well as health counseling about tobacco, sun exposure, diet and nutrition, risk factors, sexual practices, and environmental and occupational exposures.	

# American Heart Association

## Heart Disease & Stroke



# Statistics

Our guide to current statistics and the supplement to our  
Heart & Stroke Facts



2009 Update At-A-Glance

# Macro costing

**Estimated Direct and Indirect Costs (in Billions of Dollars) of CVD and Stroke: United States: 2009**

	Heart Diseases*	Coronary Heart Disease	Stroke	Hypertensive Disease	Heart Failure	Total Cardiovascular Disease
<b>Direct costs</b>						
Hospital	\$106.3	\$54.6	\$20.2	\$8.2	\$20.1	\$150.1
Nursing home	\$23.4	\$12.3	\$16.2	\$4.8	\$4.5	\$48.2
Physicians/other professionals	\$23.8	\$13.4	\$3.7	\$13.4	\$2.4	\$46.4
Drugs/other						
Medical durables	\$22.1	\$10.3	\$1.4	\$25.4	\$3.3	\$52.3
Home health care	\$7.4	\$2.2	\$4.4	\$2.4	\$3.4	\$16.8
Total expenditures	\$183.0	\$92.8	\$45.9	\$54.2	\$33.7	\$313.8
<b>Indirect costs</b>						
Lost productivity/morbidity	\$24.0	\$10.6	\$7.0	\$8.4	...	\$39.1
Lost productivity/mortality	\$97.6	\$62.0	\$16.0	\$10.8	\$3.5*	\$122.4
<b>Grand totals</b>	<b>\$304.6</b>	<b>\$165.4</b>	<b>\$68.9</b>	<b>\$73.4</b>	<b>\$37.2</b>	<b>\$475.3</b>

## **The 15 leading causes of death in 2007**

1. Diseases of heart
2. Malignant neoplasms
3. Cerebrovascular diseases
4. Chronic lower respiratory diseases
5. Accidents (unintentional injuries)
6. Alzheimer's disease
7. Diabetes mellitus
8. Influenza and pneumonia
9. Nephritis, nephrotic syndrome and nephrosis
10. Septicemia
11. Intentional self-harm (suicide)
12. Chronic liver disease and cirrhosis
13. Essential hypertension and hypertensive renal disease
14. Parkinson's disease
15. Assault (homicide)

Source: Division of Vital Statistics

# Depending on device, sample micro feasibilities need to be done

- Device is highly specialized to specific disease types
- Device is relatively costly
- Need for hospital/clinic/physician to economically justify
- Need to determine size and specialty of hospital

# Typical hospital catchment area



Primary, Secondary, Tertiary

# Hospital view of market

	Population	Estimate of Cases	Suitable	Capture
• Primary	3,624,754	16,768	400	100
• Secondary	5,693,800	26,878	650	80
• Tertiary	11,663,544	54,673	1275	20

How much revenue is this?

# Specifics of medical market revenue

- Price (to patient) determined by LCA (Lowest Cost Alternative) for replacement technologies
- Price for technologies with increased medical evidence can charge more. But medical evidence needs to be proved. This can be expensive
- Performing the procedure more precisely is not justification.
- Need to prove better results and/or less complications
- Saving time and eliminating errors may cause hospital to purchase without more reimbursement
- How is reimbursement determined?



# Specifics of medical market

- Most medical devices require FDA review

Hold for after reimbursement discussion

FDA Clearance/Approval is needed prior to any reimbursement

# What's involved in reimbursement process

- Coverage

Process of getting a service or procedure included in an insurer's package

- Coding

Process of getting a service or a procedure an "identifier" so that it can be priced as a service or bundled with another procedure that is priced

- Payment

Process by the insurer to set a price for the service or procedure

# Reimbursement Overview



Source: The Lewin Group, 2001

# Medicare National Coverage Process



# Proton Beam Radiation Therapy Codes

CPT	Description
77520	Proton treatment delivery; simple w/o compensation
77522	Proton treatment delivery; simple w/ compensation
77523	Proton treatment delivery; intermediate
77525	Proton treatment delivery; complex

# Annual Publication of CPT Coding



## Federal Register

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Tuesday,  
November 18, 2008

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### Part II

### Department of Health and Human Services

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Centers for Medicare & Medicaid Services

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42 CFR Parts 410, 416, and 419  
Medicare Program: Changes to the  
Hospital Outpatient Prospective Payment  
System and CY 2009 Payment Rates;  
Changes to the Ambulatory Surgical  
Center Payment System and CY 2009  
Payment Rates; Hospital Conditions of  
Participation: Requirements for Approval  
and Re-Approval of Transplant Centers  
To Perform Organ Transplants—  
Clarification of Provider and Supplier  
Termination Policy Medicare and  
Medicaid Programs; Changes to the  
Ambulatory Surgical Center Conditions  
for Coverage; Final Rule

# New MAC Jurisdictions



Source: CMS

# Proton Beam Procedures

<b>CPT</b>	<b>2007 Medicare Physician Fee Schedule (Free-Standing Facility)</b>			<b>2007 APC Payment (Hospital Outpatient)</b>
	<b>Global Indiana</b>	<b>Global Florida</b>	<b>Global Texas</b>	
77520	-	\$901	\$913	\$1,161.29 (APC 0664)
77522	\$516	\$932	\$945	\$1,161.29 (APC 0664)
77523	\$782	\$968	\$982	\$1,389.37 (APC 0667)
77525	\$782	\$1,108	\$1,096	\$1,389.37 (APC 0667)



# OPPS Payment—CY 2007 - CY 2008

## Proton Beam Therapy

<b>CPT Code</b>	<b>CY 2007 APC</b>	<b>CY 2008 APC</b>	<b>Per Cent Change</b>
77520	\$1,161.29 APC 0664	\$816.59 APC 0664	-29.7%
77522			
77523	\$1,389.37 APC 0667	\$977.09 APC 0667	-29.7%
77525			

Result is a reimbursement  
schedule from ONE insurer!

# Medicare

- CMS administers both Medicare & Medicaid
  - The largest single health purchaser in the world
    - FY 2003 total outlays of \$435 billion
    - Responsible for close to 40 cents of every health dollar spent in the US in FY 2002



# Private Insurance Companies

**TABLE:**  
**Showing Market Concentration of Privately Insured Individuals in the U.S.**

Rank		Total Enrollment <sup>1</sup> (Mil)	Cumulative	Percent	Cumulative %
1)	WellPoint	35	35	18.9%	18.9%
2)	UnitedHealth Group	32.9	67.9	17.8%	36.7%
3)	Aetna	17.7	85.6	9.6%	46.2%
4)	Humana	14.8	100.4	8.0%	54.2%
5)	HealthCare Service Corp	12.4	112.8	6.7%	60.9%
6)	Cigna Group	12.0	124.8	6.5%	67.4%
7)	KFHP (Kaiser Foundation)	8.6	133.4	4.6%	72.1%
8)	Highmark	4.8	138.2	2.6%	74.7%
9)	Health Net	3.7	141.9	2.0%	76.7%
	<b>Total of Top Ten Insurance Firms</b>	<b>141.9</b>	<b>141.9</b>	<b>76.7%</b>	<b>76.7%</b>
	<b>Total of All Privately Insured Individuals<sup>2</sup></b>	<b>185.1</b>		<b>100.0%</b>	<b>100.0%</b>

<sup>1</sup> Source: Company filings, public sources

<sup>2</sup> Source: "The Uninsured, A Primer", October 2008, Kaiser Family Foundation

# The Hospital's Customers (Patients)

<b>Reimbursements</b>		
<b>Payer Mix &amp; Reimbursement Level</b>	Payment as % of Gross Billing	% of Patient Volume
		<b>Gross Billing Amount</b>
Medicare	100%	35.0%
Managed Care	150%	20.0%
Commercial	135%	20.0%
Self Pay	200%	10.0%
Medicaid	100%	10.0%
Charity	0%	4.0%
Other (e.g. Personnel)	100%	1.0%

# Revenue for a particular procedure

Payor	Patient Numbers	Factor based on Medicare	Charge per patient	Total Rev for time period
Medicare	350	100%	\$80.00	\$28,000
Managed Care	200	150%	\$120	\$24,000
Commercial	200	135%	\$108	\$21,600
Self Pay	100	200%	\$160	\$16,000
Medicaid	100	100%	\$80	\$8,000
Charity	40	0%	\$0	\$0
Other (e.g. Personnel)	10	100%	\$80	\$800

Average Revenue per patient =  $\$98,400 / 1,000 = \$98.40$

# July/August 2009 Cancer Journal

## REVIEW ARTICLE

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### Proton Beam Therapy and the Convolved Pathway to Incorporating Emerging Technology into Routine Medical Care in the United States

*Michael L. Steinberg, MD,\* and Andre Konski, MD, MBA†*

**Abstract:** The pathway that emerging medical technologies take to incorporation into routine medical care in the United States is a product of the social, economic, and political milieu. Our review explores how this milieu brought the incorporation of proton beam therapy into the healthcare delivery system to its current point. We look at how new technologies are presently accepted into this system and discuss the emerging trends—such as the use of evidence-based assessment of technology, coverage with evidence policies, and comparative effectiveness analysis—that are affecting proton beam therapy's effort to find its place in the pantheon of available medical treatments for patients with cancer.

**Key Words:** technology assessment, biomedical, proton beam therapy, emerging medical technology, evidence-based medicine

*(Cancer J 2009;15: 000–000)*

One of the most contentious and controversial issues for health policy decision makers, medical providers, and the healthcare technology industry in the United States is the pathway for incorporating new and emerging medical technologies into the healthcare delivery system. And one of the medical technologies that has

economic, and political milieu brought the issue of the incorporation of PBT into the healthcare delivery system to this point. We look at how new technologies are currently accepted into this system and discuss emerging trends—such as the use of evidence-based assessment of technology, coverage with evidence policies, and comparative effectiveness analysis—affecting PBT's effort to find its place in the pantheon of available medical treatments for patients with cancer.

#### THE CURRENT HEALTH POLICY CONTEXT

Serious challenges face the United States healthcare delivery system, including the fact that despite ever-increasing healthcare costs, the United States has not yet been able to achieve health outcomes as good as or as high value as those of other industrialized countries.<sup>1</sup> Moreover, this confounding situation continues while the number of medically uninsured in the United States grows. To date, most health policy experts agree that the United States has not coherently embraced policies and processes to simultaneously enhance value and address cost.<sup>1</sup>

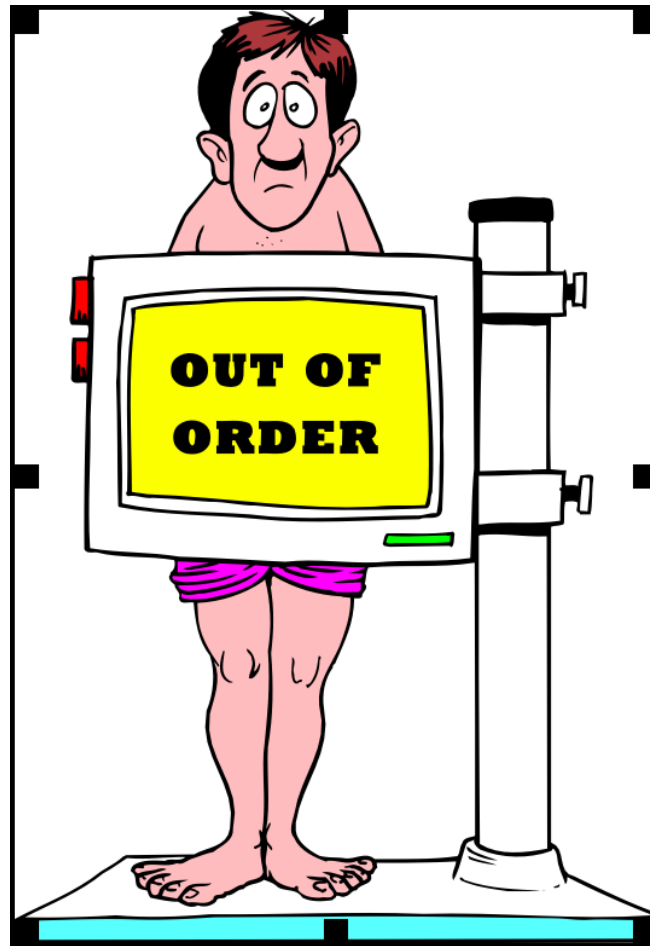
The drivers of the rising cost of U.S. healthcare are often portrayed as fraud and abuse, bureaucratic inefficiencies, and inadequate free market influences in the business of healthcare delivery.

# What are the important drivers to gain acceptance/reimbursement?

- FDA Clearance/Approval
- Lower diagnostic or treatment cost
- Evidence based results
- Reduce complications
- Reduce hospital stay
- Increase throughput
- Reduce return admissions
- Help an existing company enter market or increase share

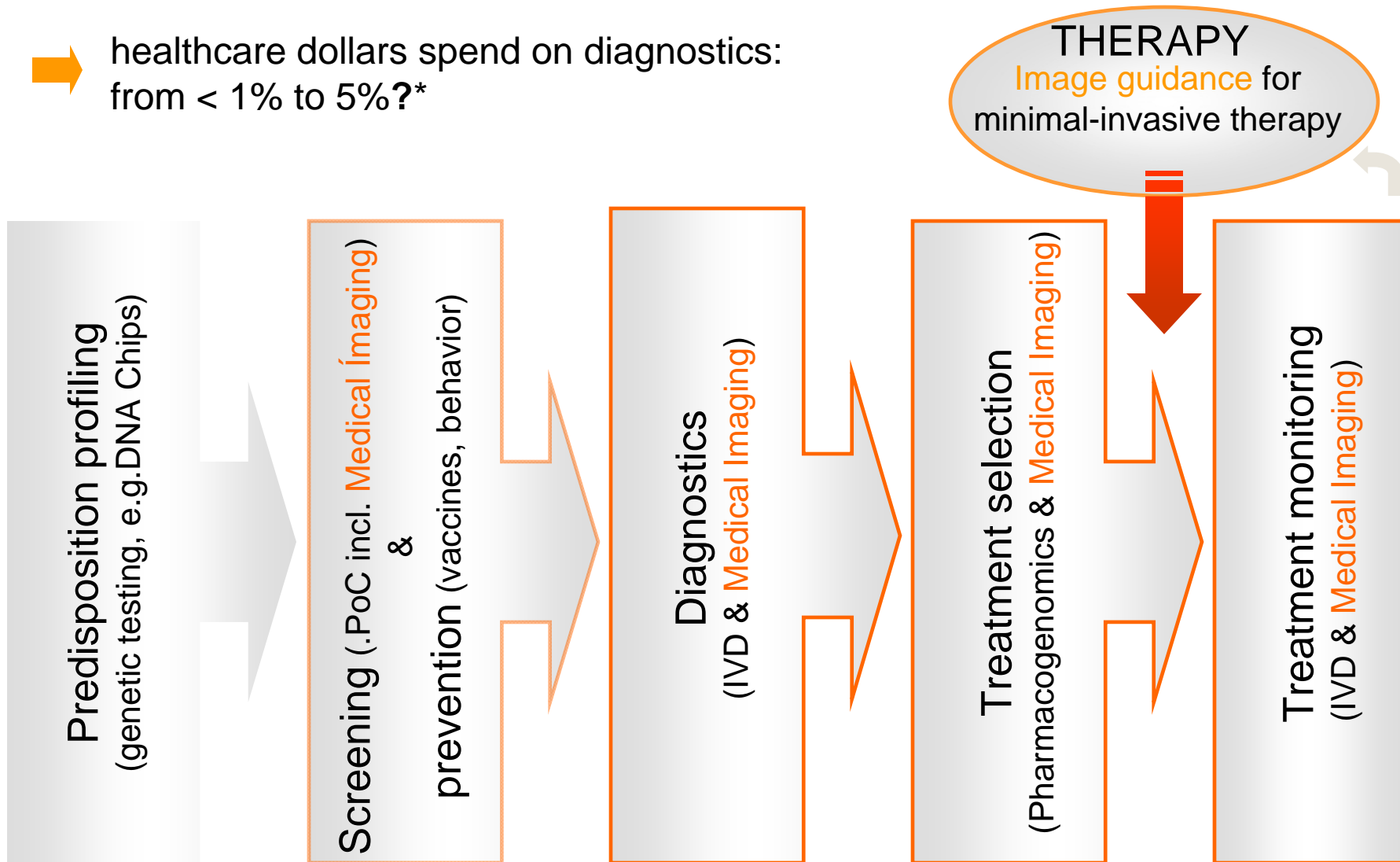


# Move to integrated approach



# Medical Imaging in the Age of Theranostics & Pharmacogenomics

➔ healthcare dollars spend on diagnostics:  
from < 1% to 5%?\*



\*market forecast (2000), Clinica reports

# Drive on to Motivate Hospitals to Prevent Avoidable Readmissions

Category: [Laboratory News](#), [Laboratory Pathology](#)

Published: August 19 2009



Rating: 4.0/5 (1 vote cast)

## ***One approach is to bundle payments to hospitals, physicians, labs, and other providers***

Momentum is building around a new effort to drive down existing rates of hospital readmissions. Different reimbursement proposals to encourage hospitals and physicians to reduce current readmission rates will likely also change the reimbursement status quo for laboratory testing. For example, bundling Part A and Part B payments may be one approach.

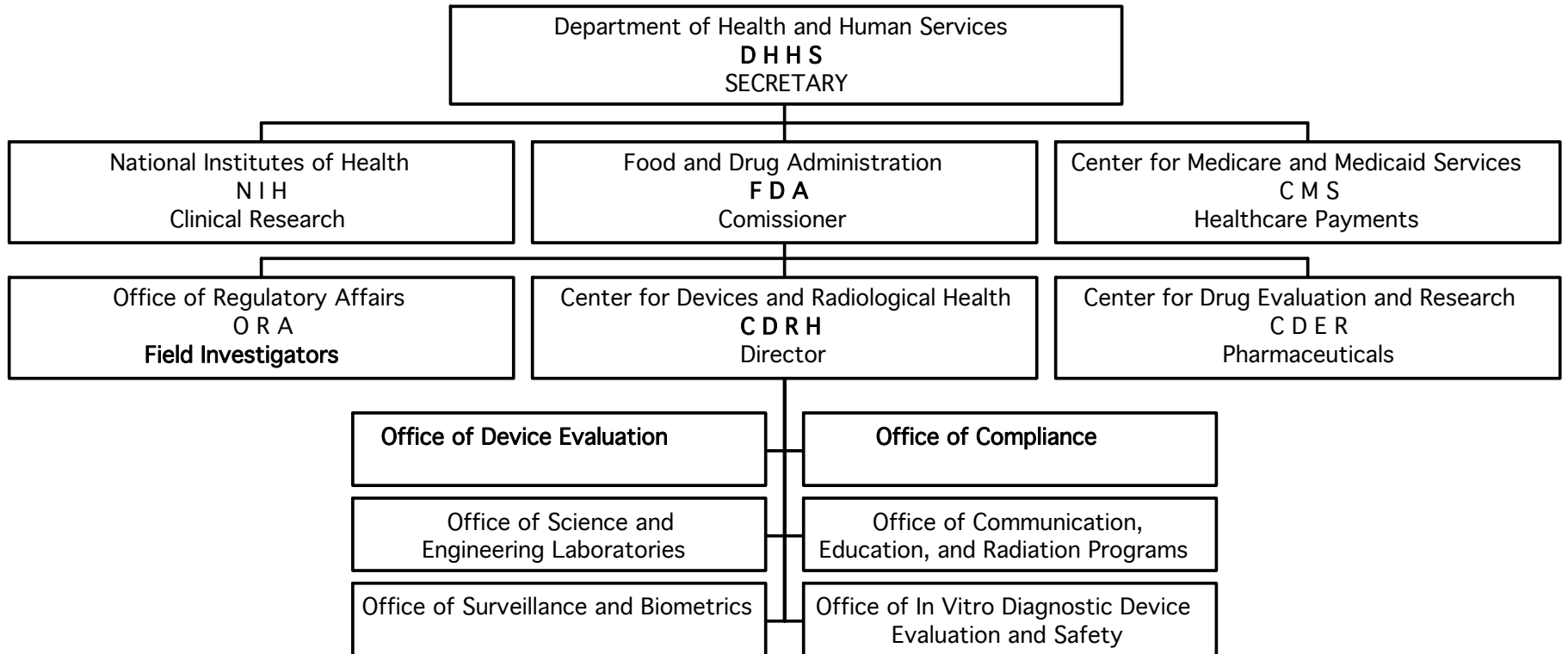
Experts increasingly believe one game changer in lowering healthcare costs and improving outcomes is avoidable hospital readmissions. One in five [Medicare](#) patients [returns to the hospital within 30 days](#). Overall, readmissions cost Medicare an estimated \$17 billion yearly. Of this total, about \$12 billion are believed to be avoidable cases

All this in a regulated environment



May 28, 1976, the Medical Device Amendments to the Food, Drug and Cosmetic Act were enacted into Law.

# FDA ORGANIZATION



# Device Intended for Human Use

Before a device can be used on humans it must have **one** of the following:

- 1. Premarket Notification [510(k)] Clearance from FDA
- 2. Premarket Approval Application (PMA) approved by FDA
- 3. Investigational Device Exemption (IDE) approved by FDA or an Investigational Review Board (IRB)

# FD&C Act: The LAW

- Prohibition of Adulteration: 501 FD&C Act
- Prohibition of Misbranding: 502 FD&C Act
- Banned devices: 516 FD&C Act
- Notification, and repair, replacement or refund: 518 FD&C Act
- Records and Reports: 519 FD&C Act
- Restricted Devices: 520 FD&C Act

# FD&C Act: The LAW

- Establishment Registration & Device Listing: 21 CFR 807
- Premarket Notification [510(k)]: 21 CFR §807.81
- Investigational Device Exemption (IDE): 21 CFR 812
- Quality System Regulation (CGMP): 21 CFR 820
- Labeling: 21 CFR 801
- Medical Device Reporting: 21 CFR 803
- Reports of Corrections and Removals: 21 CFR 806
- Electronic Records; Electronic Signatures: 21 CFR 11
- Device Identification & Classification: 21 CFR 862-892
- RHTA, Electronic Product Radiation: 21 CFR 1000-1050



21 CFR Sec. 820.30 Design controls.  
...shall establish and maintain procedures...

(a) General.

(b) Design and  
development planning

(c) Design input.

(d) Design output.

(e) Design review.

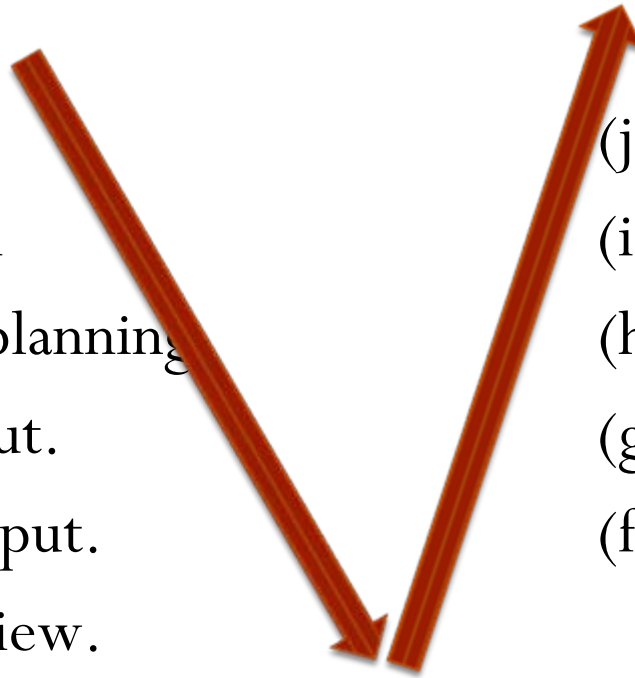
(j) Design history file.

(i) Design changes.

(h) Design transfer.

(g) Design validation.

(f) Design verification.



# Back to the start of the design...

## Time to review a few key points

- Medical market is robust with room for new innovations
- Medical market requires an understanding of reimbursement
- Medical market is well defined for estimating potential sales
- Evidence based medicine requires a lengthy process
- Regulatory issues are extensive but well documented